510(k) Summary

MAR 0 5 2014

1. Submitter Identification

510(k) Submitter	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
Address	Block 6 and 7, Zhu Keng Industrial Zone, Ping Shan, Long Gang District, Shenzhen, Guang Dong, People's Republic of China
Phone Number	(00852)-2851-6789
Fax Number	(00852)-2851-6278
Contact Person	Mr. Patrick Chow
Date of Submission	19th November, 2013

2. Device Identification

Trade Name	Digital Automatic Blood Pressure Monitor BPM18 Series [Model No.: MD18xy] x --- The first character (0, 1, 2, 3, 4, 5, 6 & 7) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1 and EN 60601-1-2. y --- The second character (0 & 1) is for the identification of cabinet (housing)
Common Name	Non-invasive Blood Pressure Measurement System
Classification Name	Non-invasive Blood Pressure Measurement System (CFR 870.1130, Class II, Product Code DXN)

3. Predicate Device

Predicate Device	Digital Automatic Blood Pressure Monitor BPM11 Series
Manufacturer	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
510(k) Number	K120675

4. Device Description

Digital Automatic Blood Pressure Monitor BPM18 Series is a non-invasive blood pressure measurement system for use by medical professional or at home. It is designed to measure the systolic and diastolic blood pressure, and pulse rate of an individual in each measurement and then display the readings on a digital panel.

The device utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the upper arm of an individual, for blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movement into a digital reading.

The table below illustrate the feature presence in Digital Automatic Blood Pressure Monitor BPM18 Series.

Model	Blood Pressure Measurement	Pulse Rate Measurement	WHO Classification	Irregular Heartbeat	LCD Type	Backlight Illumination	DC Jack	Memory
MD1800	✔	✔	✔	✔	Positive Reflective	✗	✔	2*120
MD1810	✔	✔	✔	✔	Positive Transmissive	Blue	✔	2*120
MD1820	✔	✔	✔	✔	Positive Transmissive	Orange	✔	2*120
MD1830	✔	✔	✔	✔	Negative Transmissive	White	✔	2*120
MD1840	✔	✔	✔	✔	Positive Reflective	✗	✗	2*120
MD1850	✔	✔	✔	✔	Positive Transmissive	Blue	✗	2*120
MD1860	✔	✔	✔	✔	Positive Transmissive	Orange	✗	2*120
MD1870	✔	✔	✔	✔	Negative Transmissive	White	✗	2*120
MD1801	✔	✔	✔	✔	Positive Reflective	✗	✔	2*120
MD1811	✔	✔	✔	✔	Positive Transmissive	Blue	✔	2*120
MD1821	✔	✔	✔	✔	Positive Transmissive	Orange	✔	2*120
MD1831	✔	✔	✔	✔	Negative Transmissive	White	✔	2*120
MD1841	✔	✔	✔	✔	Positive Reflective	✗	✗	2*120
MD1851	✔	✔	✔	✔	Positive Transmissive	Blue	✗	2*120
MD1861	✔	✔	✔	✔	Positive Transmissive	Orange	✗	2*120
MD1871	✔	✔	✔	✔	Negative Transmissive	White	✗	2*120

5. Indication for Use

Digital Automatic Blood Pressure Monitor BPM18 Series is for use by medical professional or home user. The BPM18 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.

6. Comparison of Technological Characteristics between New Device and Predicate Devices

Digital Automatic Blood Pressure Monitor BPM18 Series is compared to the predicate device, BPM11 Series (K120675) in the device comparison table below.

Comparison between BPM18 Series and predicate device			
Item	**Predicate Device**	**BPM18 Series**	**Comment**
Indication for Use	Digital Automatic Blood Pressure Monitor BPM11 Series is for use by medical professional or at home. The BPM11 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm - 44cm via 3 different size of cuff. 3 different cuff sizes are 17-22cm, 22-32cm and 32-44cm.	Digital Automatic Blood Pressure Monitor BPM18 Series is for use by medical professional or home user. The BPM18 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.	Equivalent
Measurement Method	Non-invasive, Oscillometric	Non-invasive, Oscillometric	Identical
Irregular Heartbeat Detection (IHB)	Yes	Yes	Identical
Patient Population	Age 16 or above	Age 16 or above	Identical
Blood Pressure Measurement Range	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Identical
Number of User	2 independent users	2 independent users	Identical
Memory Space	2 users × 120 memory space	2 users × 120 memory space	Identical
Blood Pressure Measurement Accuracy	± 3 mmHg or 2% of reading	± 3 mmHg or 2% of reading	Identical
Pulse Rate Measurement Range	30 - 180 beats/min	30 - 180 beats/min	Identical
Pulse Rate Measurement Accuracy	± 5 % of the reading	± 5 % of the reading	Identical
Display Type	LCD	LCD	Identical

Comparison between BPM18 Series and predicate device			
Item	**Predicate Device**	**BPM18 Series**	**Comment**
Power Source	4 × 1.5 V AA-batteries; and/or AC adaptor (6V/600mA)	4 × 1.5 V AAA-batteries; and/or AC adaptor (6V/600mA)	Identical
Pressurization Mode	Automatic Inflation	Automatic Inflation	Identical
Deflation Mode	Automatic Exhaust/ Deflation	Automatic Exhaust/ Deflation	Identical
Operating Condition	Temperature: 10 - 40 °C Humidity: 30 - 85 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Temperature: 10 - 40 °C Humidity: 15 - 85 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Equivalent, improved specification
Storage and Transportation Condition	Temperature: -20 - 60 °C Humidity: 10 - 95 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Temperature: -20 - 60 °C Humidity: 10 - 95 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Identical
Cuff Size (Arm circumference)	17.0 - 22.0 cm 22.0 - 32.0 cm 32.0 - 44.0 cm	17.0 - 22.0 cm 22.0 - 32.0 cm 32.0 - 44.0 cm	Identical
Material	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Identical
Compatibility with Environment and Other Devices	No influence with environment and other device	No influence with environment and other device	Identical
Applicable Standard	✧ EN 1060-1:1995/A2:2009 ✧ EN 1060-3:1997/A2:2009 ✧ IEC 60601-1:2005+ CORR.1(2006)+CORR. 2 (2007) ✧ EN 60601-1-2:2007 ✧ FCC Part 15 ✧ ISO 10993-5:2009 ✧ ISO 10993-10:2002 + A1:2006 ✧ EN 60601-1-4:2007 ✧ ANSI/AAMI SP-10:2002	✧ EN 1060-1:1995+A2:2009 ✧ EN 1060-3:1997+A2:2009 ✧ IEC 60601-1:2012 ✧ EN 60601-1-2:2007 ✧ FCC Part 15 Subpart B ✧ ISO 10993-5:2009 ✧ ISO 10993-10:2010 ✧ IEC 62304:2006 ✧ IEC 81060-2:2009	Equivalent

Digital Automatic Blood Pressure Monitor BPM18 Series is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key components of device are: a pressure sensor, a electric valve and an electronic control module together with an electric pump. The electric pump inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

7. Clinical and Non-clinical Tests

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2:2009 as documented in Clinical Test report.

One hundred patients (49 males and 51 females) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left upper arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2:2009.

Non-Clinical Test Summary

Digital Automatic Blood Pressure Monitor BPM18 Series has performed several non-clinical tests to show that all requirement specifications and standard requirements are met. The tests includes the follows:

- EN 1060-1:1995+A2:2009
- EN 1060-3:1997+A2:2009
- IEC 60601-1:2012
- EN 60601-1-2:2007
- FCC Part 15 Subpart B
- ISO 10993-5:2009
- ISO 10993-10:2010
- IEC 62304:2006

As all of the clinical and non-clinical testing performed on Digital Automatic Blood Pressure Monitor BPM18 Series are same as the predicate device. Therefore, no bench test is conducted to show the performance of Digital Automatic Blood Pressure Monitor BPM18 Series is equivalent to the predicate device.

8. Conclusion

Digital Automatic Blood Pressure Monitor BPM18 Series has the same intended use and similar technological characteristics as the predicate device, Digital Automatic Blood Pressure Monitor BPM11 Series (K120675). Moreover clinical testing has demonstrated that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, Digital Automatic Blood Pressure Monitor BPM18 Series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2014

Grandway Technology (Shenzhen) Limited
Patrick Chow
Zhu Keng Industrial Zone
Ping Shan, Long Gang District
Shenshen, Guang Dong, 518118 CH

Re: K133619
Trade/Device Name: Digital Automatic Blood Pressure Monitor BPM18 Series
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 12, 2014
Received: November 25, 2013

Dear Patrick Chow,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

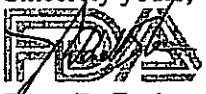
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 Indication for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Digital Automatic Blood Pressure Monitor BPM18 Series

Indications for Use *(Describe)*
Digital Automatic Blood Pressure Monitor BPM18 Series is for use by medical professional or home user. The BPM18 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Date: 2014.03.05
16:19:16 -05'00'
for Bram Zuckerman

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